§520.1196

(Strongyloides westeri (adult)); Summer Sores caused by Habronema and Draschia spp. cutaneous third-stage larvae; and Dermatitis caused by neck threadworm microfilariae (Onchocerca spp.).

(iii) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) Sheep—(i) Amount. 200 mcg/kg (3 mL/26 pounds) of body weight as a single dose oral drench.

- (ii) Indications for use. For treatment and control of the adult and fourthlarvae of gastrointestinal stage roundworms (Haemonchus contortus, H. placei (adults only), Ostertagia circumcincta, Trichostrongylus axei, T. colubriformis, Cooperia oncophora (adults only), curticei, COesophagostomum columbianum, 0 venulosum(adults only), Nematodirus battus, N. spathiger, S. papillosus (adults only), Chabertia ovina (adult only), Trichuris ovis (adults only)): lungworms (D. filaria); and all larval stages of the nasal bot Oestrus ovis.
- (iii) *Limitations*. For use in sheep only. Do not use in other animal species as severe adverse reactions, including fatalities in dogs, may result. Do not treat sheep within 11 days of slaughter.

[67 FR 50597, Aug. 5, 2002, as amended at 69 FR 57173, Sept. 24, 2004]

§ 520.1196 Ivermectin and pyrantel pamoate chewable tablets.

- (a) Specifications. Each chewable tablet contains either 68 micrograms (μ g) of ivermectin and 57 milligrams (mg) of pyrantel (as pamoate salt), or 136 μ g and 114 mg, or 272 μ g and 227 mg, respectively.
- (b) *Sponsors*. See Nos. 050604, 051311, and 063604 in §510.600(c) of this chapter.
- (c) Conditions of use—(1) Dogs—(i) Amount. A minimum of 6 µg of ivermectin and 5 mg of pyrantel (as pamoate salt) per kilogram (2.72 µg and 2.27 mg per pound) of body weight.
- (ii) Indications for use. To prevent canine heartworm disease by eliminating the tissue larval stages of Dirofilaria immitis for up to a month (30 days) after infection and treatment and control of adult ascarids Toxocara canis and Toxascaris leonina, and adult

hookworms Ancylostoma caninum, A. braziliense, and Uncinaria stenocephala.

- (iii) *Limitations*. Use monthly. Recommended for dogs 6 weeks of age and older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
 - (2) [Reserved]

[58 FR 8542, Feb. 16, 1993, as amended at 61 FR 15186, Apr. 5, 1996; 61 FR 59004, Nov. 20, 1996; 62 FR 63270, Nov. 28, 1997; 66 FR 35756, July 9, 2001; 67 FR 21996, May 2, 2002; 68 FR 55823, Sept. 29, 2003]

§ 520.1197 Ivermectin sustained-release bolus.

- (a) *Specifications.* Each sustained-release bolus contains 1.72 grams of ivermectin
- (b) Sponsor. See No. 050604 in $\S510.600$ (c) of this chapter.
- (c) Related tolerances. See § 556.344 of this chapter.
- (d) Conditions of use in ruminating calves—(1) Amount. Administer one bolus per calf weighing at least 275 pounds (lb) (125 kilograms (kg)) and not more than 660 lb (300 kg) on the day of administration.
- (2) Indications. For treatment and control, throughout the grazing season (approximately 130 days), of gastrointestinal roundworms Haemonchus placei, Ostertagia ostertagi (including inhibited fourth-stage Trichostrongylus axei, T. colubriformis, Cooperia spp., Nematodirus helvetianus, Bunostomum phlebotomum, Oesophagostomum radiatum; lungworms Dictyocaulus viviparus; grubs Hypoderma spp.; sucking lice Linognathus vituli, Solenopotes capillatus; mange mites Psoroptes ovis, Sarcoptes scabiei, and ticks Amblyomma americanum.
- (3) Limitations. The bolus was specifically designed for use in cattle; do not use in other animal species. Calves must be ruminating and older than 12 weeks of age. Do not administer to calves weighing less than 275 lb (125 kg). Do not administer a damaged bolus. Because a milk withdrawal time has not been established, do not use in female dairy cattle of breeding age. Do not slaughter cattle within 180 days of treatment. Consult your veterinarian

for assistance in the diagnosis, treatment, and control of parasitism.

[61 FR 67452, Dec. 23, 1996, as amended at 62 FR 63270, Nov. 28, 1997; 65 FR 45876, July 26, 2000]

§ 520.1198 Ivermectin and praziquantel paste.

- (a) Specifications. Each milligram (mg) of paste contains:
- (1) 0.0155 mg (1.55 percent) ivermectin and 0.0775 mg (7.75 percent) praziquantel.
- (2) 0.0187 mg (1.87 percent) ivermectin and 0.1403 mg (14.03 percent) praziquantel.
- (b) Sponsors. See sponsors in §510.600(c) of this chapter for uses as in paragraph (d) of this section.—(1) No. 050604 for use of product described in paragraph (a)(1) of this section as in paragraphs (d)(1)(i), (d)(2)(i) and (d)(3) of this section.
- (2) No. 051311 for use of product described in paragraph (a)(2) of this section as in paragraphs (d)(1)(ii), (d)(2)(ii), and (d)(3) of this section.
- (c) Special considerations. See $\S 500.25$ of this chapter.
- (d) Conditions of use in horses—(1) Amount—(i) 200 micrograms (mcg) per kilogram (/kg) ivermectin (91 mcg per pound (/lb)) and 1 mg/kg praziquantel (454 mcg/lb) body weight.
- (ii) 200 mcg/kg ivermectin (91 mcg/lb) and 1.5 mg/kg praziquantel (681 mcg/lb) body weight.
- (2) *Indications for use.* For treatment and control of:
- (i) For treatment and control of the following parasites in horses: Tapeworms—Anoplocephala perfoliata; Large strongyles (adults)—Strongylus vulgaris (also early forms in blood vessels), S. edentatus (also tissue stages), equinus, Triodontophorus spp. including T. brevicauda and T. serratus, and Craterostomum acuticaudatum; Small Strongyles (adults, including those resistant to some benzimidazole class compounds)—Coronocyclus spp. including C. coronatus, C. labiatus, and C. labratus, Cyathostomum spp. including C. catinatum and C. pateratum, Cylicocyclus spp. including C. insigne, C. catinatum and C. leptostomum, C. nassatus, and C. brevicapsulatus, Cylicodontophorus spp., Cylicostephanus spp. including calicatus, C. goldi, C. longibursatus, and

- C. minutus, and Petrovinema poculatum; Small Strongyles—fourth-stage larvae; Pinworms (adults and fourth stage larvae)—Oxyuris equi; Ascarids (adults and thirdand fourth-stage larvae)— Parascaris equorum; Hairworms (adults)—Trichostrongylus axei; Largemouth Stomach Worms (adults)-Habronema muscae; Bots (oral and gastric stages)—Gasterophilus spp. including G. intestinalis and G. nasalis; Lungworms (adults and fourth-stage larvae)-Dictyocaulus arnfieldi; Intestinal Threadworms (adults)— Strongyloides westeri; Summer Sores caused by Habronema and Draschia spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, Onchocerca sp.
- Tapeworms (Anoplocephala perfoliata); large strongyles (adults) (Strongylus vulgaris (also early forms in blood vessels), S. edentatus (also tissue stages), S. equinus, Triodontophorus spp.); small strongyles including those resistant to some benzimidazole-class compounds (adults and fourth-stage larvae) (Cyathostomum spp., Cylicocyclus Cylicostephanus Cylicodontophorus spp.); pinworms (adults fourth-stage and larvae) (Oxyuris equi); ascarids (adults and thirdfourth-stage and larvae) (Parascaris equorum); hairworms (adults) (Trichostrongylus axei); largemouth stomach worms (adults) (Habronema muscae); bots (oral and gas-(Gasterophilus tric stages) lungworms (adults and fourth-stage larvae) (Dictyocaulus arnfieldi); intesthreadworms (Strongyloides westeri); summer sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; and dermatitis caused by neck threadworm microfilariae, Onchocerca sp.
- (3) *Limitations.* For oral use only. Do not use in horses intended for human consumption.

[68 FR 55309, Sept. 25, 2003, as amended at 69 FR 49808, Aug. 12, 2004]

§ 520.1204 Kanamycin sulfate, aminopentamide hydrogen sulfate, pectin, bismuth subcarbonate, activated attapulgite suspension.

(a) *Specifications*. Each five milliliters of suspension of the drug contains: 100